

## CLAIMS

What is claimed is:

- 5 1. A dry powder inhaler for administering a dose of a medicament, said inhaler comprising:  
a reservoir holding said medicament;  
an air channel assembly engaged with, and movable relatively to, said reservoir for receiving  
said dose of medicament upon said relative motion; and  
a counter for counting a number of doses dispensed from said reservoir or that can still be  
10 delivered before the inhaler is considered empty; said counter comprising a first indicator member  
which moves one increment in response to said relative motion, and a second indicator member which  
moves intermittently in response to motion of said first indicator member, a rotatory intermittent drive  
transfer mechanism being positioned between and engageable with said first and second indicator  
members, said first indicator member driving said rotatory intermittent drive transfer mechanism, said  
15 rotatory intermittent drive transfer mechanism driving said second indicator member intermittently  
upon motion of said first indicator member, said first and second indicator members having indicia  
thereon for displaying the number of said doses dispensed from said reservoir or that can still be  
delivered before the inhaler is considered empty.
- 20 2. An inhaler according to Claim 1 adapted to administer said medicament orally.
3. An inhaler according to any one of Claims 1 or 2, wherein said reservoir is arranged  
circumferentially around a central axis, said air channel assembly being positioned coaxially with said  
reservoir and rotatably movable about said axis relatively thereto, said first indicator member and said  
25 second indicator member also being positioned coaxially with said reservoir and rotatably movable  
about said axis for counting said doses dispensed from said reservoir or doses that can still be  
delivered before the inhaler is considered empty.
4. An inhaler according to any one of Claims 1 to 3, further comprising a ratchet and pawl for  
30 connecting said first indicator member to said air channel assembly for motion of said first indicator  
member in response to motion of said air channel assembly relatively to said reservoir, said ratchet  
being mounted on one of said first indicator member and said air channel assembly and rotatable  
about said axis therewith, said pawl being mounted on the other of said first indicator member and  
said air channel assembly and engaging said ratchet for causing rotational motion of said first  
35 indicator member only in one direction about said axis.

5. An inhaler according to Claim 4, wherein said pawl is mounted on said first indicator member and said ratchet is mounted on said air channel assembly.

6. An inhaler according to Claim 4 or 5, further comprising a coupling positioned between said first indicator member and said air channel assembly, one end of said coupling interfacing with said first indicator member and comprising one of said ratchet and said pawl, the other end of said coupling having a plurality of legs extending therefrom for engaging said air channel assembly, said coupling transmitting relative motion of said air channel assembly to said counter for moving said first indicator member.

7. An inhaler according to Claim 6, wherein said ratchet is mounted on said coupling and said pawl is mounted on said first indicator member, said ratchet engaging said pawl for rotating said first indicator member about said axis in response to motion of said air channel assembly.

8. An inhaler according to any one of Claims 1 to 7, wherein said first indicator member and second indicator member rotate in the same direction during operation.

9. An inhaler according to any one of Claims 1 to 8, wherein said first indicator member has a first surface on which said indicia appear, said first surface facing radially outwardly from said axis, said second indicator member has a second surface on which said indicia appear, said second surface being transparent and facing radially outwardly from said axis, said first indicator member being nested within said second indicator member, said indicia on said first indicator member aligning with said indicia on said second indicator member and being visible therethrough to display the number of said doses dispensed from said reservoir or that can still be delivered before the inhaler is considered empty.

10. An inhaler according to any one of Claims 1 to 9, wherein said rotatory intermittent drive transfer mechanism comprises a slave wheel rotatable about an offset axis offset from said central axis and substantially parallel thereto, said slave wheel having a drive transfer wheel on one face and a gear on an opposite face.

11. An inhaler according to any one of Claims 1 to 10, wherein said first indicator member has a foot extending therefrom for engaging said drive transfer wheel, the second indicator member having gear teeth arranged circumferentially therearound for meshing with said gear on said opposite face, upon rotation of said first indicator member, said first indicator member engaging and rotating said slave wheel, said slave wheel engaging and rotating said second indicator member intermittently.

12. An inhaler according to Claim 11, wherein said foot is mounted on said first indicator member and said gear teeth are positioned on said second indicator member .

13. An inhaler according to any one of Claims 1 to 12, wherein said first indicator member comprises a unit wheel and said second indicator member comprises a tens wheel, said second indicator member moving once for every ten movements of said unit wheel.

14. An inhaler according to any preceding claim, further comprising a third, and optionally a fourth, indicator member.

15. An inhaler according to any preceding claim, further comprising a cover mounted on an end of said inhaler opposite said air channel assembly, said cover comprising a bottom and an outwardly facing sidewall extending circumferentially around said bottom, said second indicator member (e.g. a tens wheel) having a projection mounted thereon, said cover bottom comprising a stop block positioned for engaging said projection and preventing a full rotation of said second indicator member (e.g. a tens wheel) relatively to said cover.

16. A dry powder inhaler for administering a dose of a medicament, said inhaler comprising:  
a reservoir holding said medicament;  
an air channel assembly engaged with and movable relatively to said reservoir for receiving said dose of medicament upon said relative motion; and  
a counter for counting a number of doses dispensed from said reservoir or that can still be delivered before the inhaler is considered empty, said counter comprising a coupling engaging said air channel assembly and a first indicator member and imparting rotation to said first indicator member on rotation of said air channel assembly, a second indicator member which rotates intermittently in response to motion of said first indicator member , one of said wheels having a transparent side surface facing outwardly, the other of said wheels being nested coaxially within the one wheel and having an inwardly and outwardly facing side surface, said outwardly facing side surface positioned adjacent to the transparent side surface, said surfaces having indicia thereon for displaying the number of said doses dispensed from said reservoir or that can still be delivered before the inhaler is considered empty.

17. An inhaler according to Claim 16 adapted to administer said medicament orally.

18. An inhaler according to Claim 16 or 17, further comprising a rotatory intermittent drive transfer mechanism positioned between and engageable with said first indicator member and said second indicator member, said first indicator member driving said rotatory intermittent drive transfer

mechanism, said rotatory intermittent drive transfer mechanism driving said second indicator member intermittently upon motion of said first indicator member .

19. An inhaler according to Claim 18, wherein said rotatory intermittent drive transfer mechanism comprises a slave wheel rotatable about an offset axis offset from said central axis and substantially parallel thereto, said slave wheel having a drive transfer wheel on one face and a gear on an opposite face.

20. An inhaler according to Claim 19, wherein said first indicator member has a foot extending therefrom for engaging said drive transfer wheel, the second indicator member having gear teeth arranged circumferentially therearound for meshing with said gear on said opposite face, upon rotation of said first indicator member, said first indicator member engaging and rotating said slave wheel, said slave wheel engaging and rotating said second indicator member intermittently.

21. An inhaler according to Claim 20, wherein said foot is mounted on said first indicator member and said gear teeth are positioned on said second indicator member.

22. An inhaler according to any one of Claims 16 to 21, wherein said second indicator member moves one increment for every ten increments of said first indicator member.

23. An inhaler according to any one of Claims 16 to 22, wherein said reservoir is arranged circumferentially around a central axis, said air channel assembly being positioned coaxially with said reservoir and rotatably movable about said central axis relatively thereto, said first and said second indicator members also being positioned coaxially with said reservoir and rotatably movable about said central axis for counting said doses dispensed from said reservoir or that can still be delivered before the inhaler is considered empty.

24. An inhaler according to any one of Claims 16 to 23, wherein said first indicator member is nested coaxially within said second indicator member, said second indicator member having said transparent side surface.

25. An inhaler according to any one of Claims 16 to 24, further comprising a ratchet and pawl for rotating said first indicator member in response to the rotation of said air channel assembly and said coupling, said ratchet being mounted on one of said first indicator member and said coupling, and rotatable about said central axis therewith, said pawl being mounted on the other of said first indicator member and said coupling and engaging said ratchet for causing rotational motion of said first indicator member only in one direction about said central axis.

26. An inhaler according to Claim 25, wherein said pawl is mounted on said first indicator member.

5 27. An inhaler according to any one of Claims 16 to 26, wherein said ratchet comprises a plurality of teeth positioned circumferentially around said axis in spaced relation to one another, said spaced relation between said teeth being predetermined to allow lost motion between said coupling and said first indicator member.

10 28. An inhaler according to any one of Claims 16 to 27, further comprising a cover mounted on an end of said inhaler opposite said air channel assembly, said cover comprising a bottom and an outwardly facing sidewall extending circumferentially around said bottom, said second indicator member having a projection mounted thereon, said cover bottom comprising a stop block positioned for engaging said projection and preventing a full rotation of said second indicator member relatively  
15 to said cover.

29. An inhaler according to any one of Claims 16 to 28, wherein said first indicator member comprises a unit wheel and said second indicator member comprises a tens wheel.

20 30. An inhaler according to any one of Claims 16 to 29, wherein said first indicator member and second indicator member rotate in the same direction during operation.

31. An inhaler according to any one of Claims 16 to 30, further comprising a third and optionally a fourth indicator member.

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32. A counter actuatable in response to rotary motion, said counter comprising:  
a cover having a bottom and an outwardly facing sidewall extending circumferentially around said bottom;

30 a second indicator member supported on said bottom and rotatable about a central axis substantially perpendicular to said bottom, said second indicator member comprising an outwardly facing transparent side surface extending circumferentially therearound and positioned adjacent to said sidewall, counting indicia being positioned on said transparent side surface;

a first indicator member having an outwardly facing side surface extending circumferentially therearound and positioned coaxially within and adjacent to said transparent side surface, said first  
35 indicator member being rotatable about said central axis, counting indicia being positioned on said side surface and visible through said transparent side surface;

a coupling engaging said first indicator member for transmitting rotary motion to be counted thereto; and

a slave wheel rotatable about an offset axis offset from said central axis and substantially parallel thereto, said slave wheel having a drive transfer wheel on one face and a gear on an opposite  
5 face, said first indicator member engaging and rotating said slave wheel, said slave wheel engaging and rotating said second indicator member intermittently.

33. A counter according to Claim 32, further comprising a foot extending from said first indicator member for engaging said drive transfer wheel, the second indicator member having gear teeth  
10 arranged circumferentially therearound for meshing with said gear on said opposite face of said slave wheel.

34. A counter according to Claim 33, wherein:

said offset axis is fixed on said cover substantially perpendicular to said bottom;

15 said foot is attached to said first indicator member;

said gear teeth are positioned circumferentially around said second indicator member;

said drive transfer wheel is oriented facing said first indicator member for intermittent engagement with said foot when said foot passes said offset axis as said first indicator member rotates about said central axis; and

20 said gear is oriented facing said second indicator member and meshing with said gear teeth thereon, said second indicator member being rotatably moved one increment when said first indicator member rotates said drive transfer wheel upon passing said offset axis.

35. A counter according to any one of Claims 32 to 34, wherein said coupling comprises a ratchet  
25 and said first indicator member comprises a pawl for transmitting rotary motion to said first indicator member in response to the rotation of said coupling, said ratchet and said pawl being movable about said central axis and causing rotational motion of said first indicator member only in one direction about said central axis.

30 36. A counter according to any one of Claims 32 to 35, wherein said second indicator member has a projection mounted thereon and said cover bottom comprises a stop block positioned for engaging said projection and preventing a full rotation of said second indicator member relatively to said cover.

35 37. A counter according to any one of Claims 32 to 36, further comprising a third, and optionally a fourth, indicator member.

38. A counter according to any one of Claims 32 to 37, further comprising:

an inwardly facing surface extending circumferentially around said first indicator member and positioned in the plane of said slave wheel;

a plurality of receptacles positioned circumferentially around said drive transfer wheel for receiving said foot for rotating said drive transfer wheel; and

a plurality of lobes positioned on said slave wheel between said gear and said drive transfer wheel and extending radially outwardly therefrom, each of said lobes being aligned with one of said receptacles on said drive transfer wheel, two adjacent said lobes engaging said inwardly facing surface as said first indicator member rotates relatively to said slave wheel thereby preventing inadvertent rotation of said slave wheel and thus said second indicator member.

39. A counter according to Claim 38, further comprising:

a notch positioned in said inwardly facing surface of said first indicator member adjacent to said foot; and

one lobe of said slave wheel being received within said notch when said foot engages one of said receptacles aligned with said one lobe to rotate said slave wheel, said notch providing clearance between said lobe and said inwardly facing side surface allowing said slave wheel to incrementally rotate about said offset axis, another of said lobes engaging said inwardly facing side surface upon incremental rotation of said slave wheel thereby again preventing rotation of said slave wheel until said foot again engages one of said receptacles aligned with said other lobe on said drive transfer wheel.

40. A counter according to any one of Claims 32 to 39, wherein said first indicator member comprises a unit wheel and said second indicator member comprises a tens wheel, said second indicator member moving once for every ten movements of said unit wheel.

41. A counter according to any one of Claims 32 to 40, wherein said first indicator member and second indicator member rotate in the same direction during operation.

42. A slave wheel for incrementally rotating a first indicator member intermittently in response to rotation of a second indicator member, said slave wheel otherwise preventing rotation of said first indicator member and comprising:

a first face having a rotatory intermittent drive transfer wheel positioned thereon, said drive transfer wheel having a plurality of receptacles spaced circumferentially therearound;

a second face positioned opposite said first face and having a gear thereon; and

a plurality of outwardly extending lobes positioned between said drive transfer wheel and said gear, each of said lobes being aligned with a respective receptacle on said drive transfer wheel.

43. A slave wheel according to Claim 42, in which said first indicator member is rotatably mounted and has gear teeth positioned circumferentially therearound, said second indicator member is rotatably mounted and has a circumferential surface with a notch therein and a foot extending therefrom and positioned adjacent to said notch, and wherein:

said slave wheel is rotatably mountable between said first and second indicator members, one of said lobes on said slave wheel engaging said circumferential surface on said second indicator member, thereby preventing inadvertent rotation of said slave wheel as said second indicator member rotates;

each of said receptacles on said drive transfer wheel is adapted for receiving said foot, said drive transfer wheel being rotatable incrementally by said second indicator member when said foot engages one of said receptacles and, said lobe aligned with said one receptacle is received within said notch, said notch providing clearance between said lobe and said circumferential surface allowing said slave wheel to incrementally rotate, another of said lobes engaging said circumferential surface after said incremental rotation of said slave wheel, thereby again preventing rotation of said slave wheel until said foot again engages another one of said receptacles and, said lobe aligned with said other receptacle is received in said notch; and

wherein rotation of said drive transfer wheel causes rotation of said slave wheel and thereby rotation of said gear, said gear meshing with said teeth on said first indicator member and driving said first indicator member in response to rotation of said gear.

44. A slave wheel according to Claim 42 or 43, wherein said first indicator member comprises a unit wheel and said second indicator member comprises a tens wheel, said second indicator member moving once for every ten movements of said unit wheel.

45. An inhaler according to any one of Claims 42 to 44, wherein said second indicator member moving once for every ten movements of said unit wheel.

46. An inhaler according to any one of Claims 42 to 45, wherein said first indicator member and second indicator member rotate in the same direction during operation.

47. An inhaler according to any one of Claims 42 to 46, further comprising a third and optionally a fourth indicator member.

48. A method for treating a respiratory disorder in a patient comprising the step of inhaling by a patient in need of such treatment, a therapeutically effective amount of a medicament using the dry powder inhaler of any one of Claims 1 to 31.



49. The method of Claim 47, wherein the respiratory disorder is selected from the group consisting of asthma, chronic obstructive lung disease, cystic fibrosis, or pneumonia.

5 50. The method of Claim 47, wherein the medicament is selected from the group consisting of bronchodilators, antihistamines, lung surfactants, antiviral agents, corticosteroids, ant-inflammatory agents, anti-cholinergics, and antibiotics.

51. A method for treating a respiratory disorder in a patient comprising the steps of:  
10 providing the dry powder inhaler of any one of Claims 1 to 31;  
actuating the medicament into the patient;  
causing the counter to indicate the number of metered dosages dispensed from said reservoir or that can still be delivered before the inhaler is considered empty.

15 52. A method for treating a respiratory disorder in a patient comprising the steps of:  
providing a dry powder inhaler device comprising a medicament and a counter of any one of claims 32-41;  
actuating the medicament into the patient;  
causing the counter to indicate the number of metered dosages dispensed from the inhaler or that can  
20 still be delivered before the inhaler is considered empty.

53. A method for indicating the number of metered dosages of medicaments dispensed from a dry powder inhaler, or that can still be delivered before the inhaler is considered empty, using the dry powder inhaler of any one of Claims 1 to 31.

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54. A method for indicating the number of metered dosages of medicaments dispensed from a dry powder inhaler, or that can still be delivered before the inhaler is considered empty, using a dry powder inhaler comprising the counter of any one of Claims 32 to 41.

30 55. A method for indicating the number of metered dosages of medicaments dispensed from a dry powder inhaler, or that can still be delivered before the inhaler is considered empty, using a dry powder inhaler comprising the slave wheel of any one of Claims 42 to 44.

56. A method of administering a dose of a medicament to a patient in need thereof, from a dry  
35 powder inhaler, said method comprising the steps of:  
providing a reservoir holding said medicament, said reservoir fits coaxially within a barrel, and a mandrel of an air channel assembly fits coaxially within the reservoir;

providing an air channel assembly comprising a mouthpiece, or nasalpiece, a collar and a mandrel, said air channel assembly engaged with, and movable relatively to, said reservoir for receiving said dose of medicament upon said relative motion;

providing a counter for counting a number of doses dispensed from said reservoir or that can still be delivered before the inhaler is considered empty, said counter comprising a first indicator member which moves one increment in response to said relative motion, and a second indicator member which moves intermittently in response to motion of said first indicator member;

providing a rotatory intermittent drive transfer mechanism positioned between and engageable with said first and second indicator members, said first indicator member driving said rotatory intermittent drive transfer mechanism, said rotatory intermittent drive transfer mechanism driving said second indicator member intermittently upon motion of said first indicator member, said first and second indicator members having indicia thereon for displaying the number of said doses dispensed from said reservoir or that can still be delivered before the inhaler is considered empty; and

rotating the cap and barrel relative to one another through an angle of about 105° about the central axis with the cap rotating clockwise and the barrel counterclockwise when viewed from the cap end of the inhaler;

engaging a tab in said cap which engages a notch in the collar, causing the entire air channel assembly to rotate clockwise along with the cap;

then rotating the cap and barrel in the reverse direction through the same angle;

reciprocally rotating the cap and air channel assembly causing a metered dose of powdered medicament to be scraped from the reservoir and deposited in the air channel assembly;

removing the cap,

placing the patient's lips or nasal passage on the mouthpiece, or nasalpiece; and inhaling.

57. A device for administering a dose of a medicament to a patient in need thereof, comprising: an air channel assembly comprising a mandrel;

a counter comprising a coupling, a first indicator member, a slave wheel, a second indicator member and a cover in which the first indicator member, slave wheel and second indicator member are

rotatably mounted, wherein the coupling has a plurality of legs which extend from the counter into the barrel and engage tabs on the mandrel of the air channel assembly, wherein the legs are arranged in spaced relation to one another so as to provide for lost motion between the mandrel and the coupling, wherein on the coupling opposite to the legs is mounted a ratchet which engages inner pawls on the first indicator member; and

a second ratchet positioned on the end of the barrel,

wherein the second ratchet faces radially inwardly to engage outer pawls which are mounted on the first indicator member.

58. The device of according to Claim 57, wherein the air channel assembly is capable of forward rotation through about 105°, said rotation is transmitted to the first indicator member by the coupling, wherein the legs engage the mandrel on the air channel assembly to transmit the motion, wherein the forward rotation of the coupling causes the ratchet on the coupling to forward rotate relatively to pawls on the first indicator member, resulting in the pawls slipping over the ratchet teeth and being positioned on the other side of the teeth, so that the position of the pawls and teeth are such that they are ready to move the first indicator member upon the reverse rotation of the air channel assembly.

59. The device of according to Claim 58, wherein the first indicator member is prevented from forward rotating, when the pawls engage and slip over the teeth, by the second ratchet located in the barrel, engaged by outer pawls on the first indicator member.

60. The device of according to Claim 59, wherein the air channel assembly is capable of reverse rotation through about 105°, causing the loading of a dose of medicament into the air channel assembly; and causing the counter to indicate the number of metered dosages dispersed from the dry powder inhaler or that can still be delivered before the inhaler is considered empty.

61. An inhaler according to any one of Claims 57 to 60, wherein said first indicator member comprises a unit wheel and said second indicator member comprises a tens wheel, said second indicator member moving once for every ten movements of said unit wheel.

62. An inhaler according to any one of Claims 57 to 61, wherein said first indicator member and second indicator member rotate in the same direction during operation.

63. An inhaler according to any one of Claims 57 to 62, further comprising a third and optionally a fourth indicator member.

64. An article of manufacture, comprising the inhaler of any one of Claims 1 to 31 packaged within containing means, and instruction means for using the inhaler.

65. The article according to Claim 64, wherein the instructions means is a label or tag attached to the packaging, a printed package insert, or a combination thereof.

66. The article according to Claim 64, further comprising a dry powder medication, instruction means for assembly of the inhaler, instruction means for use of the inhaler, or a combination thereof.

67. An inhaler substantially as described with reference to the accompanying drawings.

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68. A counter substantially as described with reference to the accompanying drawings.

69. A slave wheel substantially as described with reference to the accompanying drawings.